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26830 7590 02/17/2011 RICHARD COALE WILLSON JR RC Willson 3205 HARVEST MOON DR STE 200 PALM HARBOR, FL 34683-2127				
EXAMINER SIMS, JASON M				
ART UNIT		PAPER NUMBER		
1631				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rwillso@verizon.net
rwillso@gmail.com

Office Action Summary

Application No.

10/057.270

Applicant(s)

FOX ET AL.

Examiner

JASON M. SIMS

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10, 19, 21, 23, 24, 28, 29 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-10, 19, 21, 23, 24, 28, 29 and 39-47 is/are rejected.
- 7) ☒ Claim(s) 4, 10 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/2010 has been entered.

Applicant's arguments, filed 8/9/2010, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 8/9/2010, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-47 are the current claims hereby under examination.

Claim Objections

The objection to claim 9 is withdrawn because of applicant's amendment.

Claim 4 is objected to because it recites the typographical error at step F), line 1 "probesrepresenting." Claim 4 is further objected to for not appropriately ending with a period. Appropriate correction is required.

Claim 10 is objected to because step E) ends with a period indicated the end of the method steps, wherein there are further method steps recited in claim 10.

Appropriate correction is required.

Claim 40 is objected to as step C do not end with any punctuation. Appropriate correction is required.

Claim Rejections - 35 USC § 112 First Paragraph

Response to Arguments

Applicant's arguments with respect to the rejection of claim 9 under 35 USC 112 First paragraph, filed 8/9/2010 have been fully considered and are persuasive because of applicant's arguments and amendments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112 Second Paragraph

Response to Arguments

Applicant's arguments with respect to the rejection of claims under 35 USC 112 Second paragraph, filed 8/9/2010 have been fully considered and are persuasive because of applicant's arguments and amendments. Therefore the rejection has been withdrawn.

The following rejections are being newly applied, which have been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-47 and all claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 (and all claims dependent therefrom) comprise step D, which recites "tabulating in a programmed computer the extent to which the presence of the characteristic of each node in the bifurcating node phylogenetic tree of genetic relationships.," which has been deemed as vague and indefinite. Step D is unclear as to what the method step actually tabulates. Clarification via clearer claim wording is required.

Claims 4 and 10 (and all claims dependent therefrom) recite the limitation "the signature database" in line 1 of step E of claim 4 and line 1 of step F of claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 (and all claims dependent therefrom), step A, recites the method step of "obtaining or creating a nucleic acid sequence database of at least 12 of the same target nucleic acid," which has been deemed as vague and indefinite. It is unclear as to 12 of what are being obtained or created in said step. Clarification via clearer claim wording is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-9, 19, 21, 24, and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al. (US P/N 6,797,817).

The claims are directed to a method for determining the genetic affinity of organisms or viruses in a test sample containing a nucleic acid comprising the steps of:

A) Obtaining or creating a nucleic acid sequence database of the same target nucleic acid, from all organisms or viruses that will be incorporated into the determination;

B) Obtaining or developing a bifurcating node phylogenetic tree having multiple nodes that establishes the genetic affinity between substantially all the organisms or viruses included in the nucleic acid sequence databases;

C) Optionally computationally fragmenting each target nucleic acid sequence such fragmentation being performed in a programmed computer so as to create a

subsequence database of nucleic acid subsequences of length N that occur in at least two sequences in the nucleic acid database, where N is at least seven;

D) Tabulating in a programmed computer the extent to which the presence of each particular nucleic acid sequence of length N is characteristic of each node in the bifurcating node phylogenetic tree of genetic relationship by examining the occurrence frequency of each subsequence in the target nucleic acid of the organisms and viruses encompassed by or not encompassed by each node in the tree; to create a database of characteristic signature sequences;

E) Deriving a plurality of signature probes from a signature-database of characteristic signature sequences that will be complementary to a portion of the target nucleic acid sequence of the organism or virus if the signature sequence is present;

F) Hybridizing the signature probes to the target nucleic acid obtained from the test sample under conditions where a detectable signal will be produced by signature probes that hybridize to the target nucleic acid of the organism or virus and detecting such signals;

G) Identifying the nodes in the bifurcating node phylogenetic tree of genetic relationship that are represented by the signature probes that produced detectable signal, in order to determine the genetic affinity of the organism or virus in the test sample.

With regards to limitations of claims 4, 40, 43, and 45: Ebersole et al. teach at Col. 9, lines 35-45 that a phylogenetic Tree of Life was obtained and used for extracting sequences that represented the major microorganism domains, Bacteria and Archaea,

which could be used as signature sequences for obtaining signature probes for testing for the presence of dechlorinating bacteria. Ebersole et al. further teach at the abstract, Figs. 1 – 2, and col. 5, lines 27-34, that the 16s rRNA regions, i.e. the target nucleic acid, are analyzed from the samples and organisms wherein their profiles/sequence database have been created, which reads on steps A) – B). Step C) is an optional step, not necessarily performed in the instant method. However, Ebersole et al. at col. 5, lines 40-45 and col. 9, lines 11-19 and line 46 teach identifying consensus sequences, which are subsequences which occur most frequently in the 16S target nucleic acid of the organisms from which a 16s DNA profile was created. Ebersole et al. further teach at col. 9, lines 54-56 examples of the consensus sequences wherein the sequences are of length 7 or more (see SEQ ID NO: 34), which reads on limitations of step C). Ebersole et al. further teach at col. 4, lines 55-67 and col. 5, lines 1-4, lines 40-45, col. 8, lines 1-19, col. 9, lines 11-19 and lines 54-56 using sequence analysis software in a computer to analyze the consensus sequence, wherein the consensus sequences were found in each dechlorinating organism, and that the use of particular sequences, i.e. signature regions/sequences, may be used to identify dechlorinators as well as for genetic sub-typing of species. In addition, Ebersole et al. at col. 5, lines 60-62 teach identifying diagnostic sequences, which are subsequences which occur in at least two other sequences in the 16S target nucleic acid of the organisms from which a 16s DNA profile was created. Ebersole et al. further teach at col. 4, examples of the diagnostic sequences wherein the sequences are of length 7 or more (see SEQ ID NO: 31 or 32), which reads on limitations of step C). Ebersole et al. further teach at col. 4,

lines 55-67 and col. 5, lines 1-4, lines 40-45, col. 8, lines 1-19, col. 9, lines 11-19 and lines 54-56 using sequence analysis software in a computer to analyze the consensus sequence, wherein the consensus sequences were found in each dechlorinating organism, and that the use of particular sequences, i.e. signature regions/sequences, may be used to identify dechlorinators as well as for genetic sub-typing of species. Furthermore, Ebersole et al. teach at col. 9, lines 46-54 that signature regions of subsequence length N (7 or more) were analyzed and found to be characteristic of different organisms, which reads on limitations of step D) and claim 45. Ebersole et al. teach at col. 4, lines 55-67 and col. 5, lines 1-4, that sequence profiles, from which signature probes are derived, may be used to identify and subtype bacteria with similar metabolic pathways. Therefore, a signature probe may be used to identify a dechlorinated bacteria and/or bacteria with similar metabolic pathways, such as subspecies of dechlorinates, which further reads on steps E) - G). Ebersole et al. at col. 5, lines 34-39, col. 6, lines 31-34, col. 6, lines 58-67, and col. 7, lines 1-9 teach using signature sequences for generating probes and defines the use of probes and hybridization as such that is consistent in the art, which produce detectable signals, which further reads on step E). Ebersole et al. further teach at col. 2, lines 51-65, the use of signature probes in hybridizing to identify sequences such that a signal is detectable, which further reads on step F). Ebersole et al. teach at col. 8, lines 38-40 that the sequences are useful for the identification of new dechlorinating bacteria, as well as for sub-typing strains of Dehalococcoides ethenogenes. Furthermore, Ebersole et al. teach at col. 9, lines 19-40 that sequences used for obtaining probes and closest

or nearest organisms to these sequences were determined, which further reads on step G).

Ebersole et al. suggest, but do not explicitly teach tabulating the extent to which the presence of each particular subsequence of length N is characteristic of each node in the bifurcating phylogenetic tree of genetic relationship by examining the occurrence frequency of each subsequence in the target nucleic acid to create a database of characteristic signature sequences.

Ebersole et al. suggest this because they teach at col. 5, lines 40-45 and col. 9, lines 11-19 and lines 46-56 using software to analyze the consensus sequence, which are a set of bases which occur most often in the 16S sequences of the organisms and are characteristic of the group of dechlorinating organisms. Ebersole et al. further teach determining signature regions and sequences for identifying particular organisms, which are characteristic of those organisms.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have tabulated the extent to which the presence of each particular subsequence of length N is characteristic of each node in the bifurcating phylogenetic tree of genetic relationship by examining the occurrence frequency of each subsequence in the target nucleic acid to create a database of characteristic signature sequences in the method taught by Ebersole et al. This is because Ebersole et al. already considers how particular sequences are characteristic of individual and groups of organisms. One of skill in the art would have recognized that applying the known

technique of tabulating the extent to which the sequences were characteristic of each node (i.e. group or individual organism) would have yield predictable results.

Ebersole et al. teach claims 5 and 41 -42 at col. 2, lines 50-59 wherein rDNA are used for obtaining probes, which reads on the use of DNA for comprising signature probes.

Ebersole et al. teach claim 6 at col. 6, lines 58-67 wherein hybridization is taught which is consistent in the art wherein a hybridization step is done in solution, which reads on claim 6.

Ebersole et al. teach claim 7 at col. 13, lines 25-30 wherein it is taught that probes which generate a detectable signal are used, which makes obvious a probe wherein the detection step utilizes radioactive labels, chemiluminescence, and/or fluorescence.

Ebersole et al. teach claim 9, of defining a grouping of a specific species, i.e. dechlorinating bacteria, see Col. 9, lines 35-45.

Ebersole et al. suggest, but do not explicitly teach wherein the tree comprises 11 or more nodes as in claim 39 and a limitation in claim 45.

Ebersole et al. suggest this because they teach at col. 1-2 a method of identifying several species of dechlorinating bacteria, which uses phylogenetic relationships. Ebersole et al. further teach at col. 2, lines 60-65 being able to identify new strains of dechlorinating bacteria.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used a tree comprising 11 or more nodes for use in the method

of identifying bacteria as taught by Ebersole et al. This is because Ebersole et al. teach a method of using a tree of nodes for help in identifying dechlorinating bacteria. It would have been obvious to one of ordinary skill in the art that as new/ i.e. more dechlorinating bacteria are identified, see col. 2, lines 60-65, that any phylogenetic tree used in the identification process would also comprise more nodes. Therefore, the use of 11 or more nodes in a phylogenetic tree as opposed to fewer than 11 nodes, is a result of an optimized parameter and not the product of innovation. The differences between the claimed invention and the prior art were encompassed in known variation or in a principal known in the prior art.

Ebersole et al. suggest, but do not explicitly teach where the same target nucleic acid sequence is obtained from at least 12 organisms or viruses as in claim 44 and a limitation of claim 45.

Ebersole et al. suggest this because they teach at col. 1-2 a method of identifying several species of dechlorinating bacteria, which uses phylogenetic relationships and several nucleic acid sequences. Ebersole et al. further teach at col. 2, lines 60-65 being able to identify new strains of dechlorinating bacteria.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the same target nucleic acid sequence obtained from at least 12 organisms or viruses for use in the method of identifying bacteria as taught by Ebersole et al. This is because Ebersole et al. teach a method of using a tree of nodes for help in identifying dechlorinating bacteria. It would have been obvious to one of ordinary skill in the art that as new/ i.e. more dechlorinating bacteria are identified, see

col. 2, lines 60-65, that more sequences would be used in the identification process. Therefore, the use of sequences from 12 or more organisms or viruses is a result of an optimized parameter and not the product of innovation. The differences between the claimed invention and the prior art were encompassed in known variation or in a principal known in the prior art.

Ebersole et al at col. 9 and col. 10, teach using consensus sequences for identifying signature regions, i.e. signature sequences, wherein the sequences comprise at least 12 (see the 16s rDNA base substitutions of the consensus sequences, which when taken independently or together are usable for a diagnostic for dechlorinating bacteria), and the consensus sequences are at least 30% identical over at least one subsequence of at least 50 nucleotides (see SEQ ID NO: 34) as in claim 46.

Ebersole et al. teach at col. 9, lines 46-65 teach using consensus sequences of length 7 or longer that occur in all the dechlorinating isolates when creating a profile, i.e. database of signature sequences as in claim 47.

Response to Arguments

Applicant's arguments filed 8/9/2010 have been fully considered but they are not persuasive.

Applicant argues at page 15, that in Ebersole et al. the target sequences are not the sequences of the non-dechlorinating bacteria extracted from the RDP database. In

contrast claim 4, step A and claim 40 step A specify that the sequences extracted from database of sequences are the target sequences.

Applicant's arguments are not found persuasive as claim 4, step A and claim 40, step A recite a step of either Obtaining or creating a nucleic acid database and Ebersole et al. at col. 2 lines 50-67 through col. 3, lines 1-40 a list of sequences which comprises at least 12 nucleic acid sequences, from a target 16S rDNA from dechlorinating bacteria that will be incorporated into the determination.

Applicant further argues at page 16 that the instant invention all subsequences of length N in the extracted sequences are analyzed to determine their utility.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention as claim 4 does not necessitate said analytical step.

Applicant further argues that the target sequences in the instantly claimed invention are different from the target sequences used by Ebersole et al., i.e. the latter are not representative of the tree of life because they can not address any taxon above that of the node containing the dechlorinating bacteria.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The claimed invention does not require the tree of life to have nodes above a particular taxon, only the development of a phylogenetic tree having multiple nodes that establishes the genetic affinity between the organisms in the sample.

Applicant's argues that the purpose of step C is to remove from consideration all subsequences of length N where N is seven or more that never occur in the nucleic acid sequence database of step B.

Applicant's arguments are not found persuasive while that may be the intention of step C, step C remains an optional step, not one that is conditional on particular criteria, i.e. the intended criteria as recited in applicant's arguments. Therefore, applicant's arguments directed towards Ebersole not teaching step C are not found persuasive as step C is optional and not required to be taught by Ebersole et al. Applicant's arguments would be further considered if step C was rewritten to be a necessary step under particular condition', such as those recited in applicant's arguments as the intentions for step C.

Applicant argues at page 18 that the use of consensus sequences by Ebersole teaches away from the instant invention, which teaches instead (in the specification) that sequences that are not perfect or even near perfect signatures for a specific grouping may still be useful.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. Claim 4 does not recite said use or necessitate said use of consensus sequences, but merely deriving signature probes, step E, hybridizing the signature probes, step F, and identifying the nodes that are represented by the signature probes that produce detectable signal, step G.

Applicant further argues that the claimed invention teaches it is best to consider all subsequences of length N, wherein Ebersole et al. teach a method that may overlook subsequences that do not occur in a “probably region for signature sequences.”

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The instantly claimed method, claims 4, 10, and 40 does not require a consideration of all subsequences of length N. For example, claim 10 also includes the optional step C, which optionally creates a database of subsequences of length N that occur. As an optional step, and because steps D and E depend from optional step C, as evidenced by reciting limitations directed at the created subsequences in Step C, said steps D and E are also optional depending on whether step C is performed. Therefore, steps C, D, and E of claim 10 are not required to be taught in the prior art as they recite optional steps.

Applicant further argues at page 19 that the claimed invention's probes to various higher groupings are also present whereas Ebersole uses probes that distinguish members of a single grouping and possibly lower subgroupings.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. For example, the claimed invention requires only those organisms that are to be incorporated into the determination to be included. Therefore, the incorporation of only dechlorinating bacteria and lower subgroupings as taught by Ebersole et al. continue to read on the claimed invention.

Applicant again argues at page 20 that Ebersole et al. are actually teaching away from applicant's invention by teaching the use of “signature regions.” Applicant further

argues that the claimed invention examines all subsequences of length N not just signature regions.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The claimed invention does not necessitate the examination of all subsequences of length N. The only step of creating subsequences of length N is optional in the claimed method and thus not required to be taught by the prior art.

Applicant at page 22 and 29 and 31 argues that claim 4, step G uses the specific phylogenetic relations for the final identification process.

Applicants arguments are not found persuasive as Ebersole et al. at example 2 describe using a phylogenetic overview to identify species.

Applicant argues at page 24 that the instant invention incorporates probes at multiple taxonomic levels not just that of a single species or genus and even in instances when the genus or species of an organism were not represented it would still be possible to recognize that something unexpected is present.

Applicant's arguments are not found persuasive because the signature probes derived from step E, would be possible to recognize something that is present if the signature sequence is present, which would hold true in the method taught by Ebersole et al. and the taught use of the signature probes. The claimed method does not necessitate incorporating probes at multiple taxonomic levels.

Again applicant argues at paged 26-28 where the claimed method seeks to obtain signature sequences for every node in the tree that defines the phylogenetic

relationships and at nodes representing every taxonomic level in the tree instead of just one.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The instantly claimed method does not require creating a phylogenetic tree of live comprising nodes representing every taxonomic level. It only requires a tree having nodes that establish the genetic affinity between the organisms or viruses in the created nucleic acid database, which reads on one taxonomic level if that is the only level of organisms where sequences are derived.

Applicant argues at page 30 that the instant invention the database represents multiple nodes at various taxonomic levels, which is distinct from that taught by Ebersole et al.

Applicant's arguments are not found persuasive as the claimed invention does not require creating a phylogenetic tree of live comprising nodes representing every taxonomic level. It only requires a tree having nodes that establish the genetic affinity between the organisms or viruses in the created nucleic acid database, which reads on one taxonomic level if that is the only level of organisms where sequences are derived. Ebersole is incorporating only dechlorinating bacteria. Ebersole's invention can detect known bacteria and also unknown or new bacteria, which reads on the instant claims which do not necessitate organisms from different groups to be present but rather a method for determining the affinity of organisms that are present. Therefore, a method which identifies previously unknown dechlorinating bacteria, but determines they are indeed dechlorinating bacteria, inherently determines the genetic affinity of the detected

organism. In addition, Ebersole looks at all the sequences in the 16s rRNS database for analysis, see Col. 9, lines 30-40 wherein subsequences which were characteristic of the node were examined, i.e. sequences 1 and 34.

Applicant argues at pages 31-32 that the claimed invention is distinct from the method taught by Ebersole et al. in that it uses a phylogenetic tree of life for two purposes, i.e. to initially identify target sequences and then interpret probe results.

Applicant's arguments are not found persuasive as Ebersole et al. uses the tree to derive target sequences wherein "such probes derive from the observation that parts of the 16S and 23s ribosomal RNA sequences vary in different species. This information was used initially for phylogenetic analyses."

Applicant further argues that use of probes targeting multiple groupings at various taxonomic levels has the unexpected benefit of being able in one assay to detect the presence of an organism without preconceived notions that it may or may not be present.

Applicant arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The claimed invention does not recite using probes targeting multiple groupings at various taxonomic levels, but deriving signature probes that will be complimentary to a target if the signature sequence is present. Furthermore, Ebersole et al. using probes to target organisms at one taxonomic level and identify other organisms at the same or lower taxonomic level also use probes targeting multiple groupings at various taxonomic levels.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al. (US P/N 6,797,817) as applied to claim 4 above, and further in view of Coleman et al. (US P/N 6,738,502).

Ebersole et al. teach claim 4 as described above in the instant office action.

Ebersole et al. suggest do not explicitly teach generating the bifurcating phylogenetic tree of relationship by parsimony method.

Ebersole et al. suggest this because they teach using and creating a phylogenetic tree of organisms and in particular bacteria.

Coleman et al. teach at col. 2, lines 45-49 and col. 5, lines 50-57 a method directed to using 16S rRNA sequence information to deduce a phylogenetic relationship based on a parsimony method.

It would have been obvious to one ordinary skill in the art at the time of the instant invention to have used a parsimony method for creating a phylogenetic relationship as taught by Colman et al. for use in the method of using sequences and phylogenetic relationships for identifying bacteria as taught by Ebersole et al. Creating a phylogenetic tree by a parsimony method is a well known method as taught by Coleman et al. One of ordinary skill in the art would have substituted one known element, i.e. deducing a phylogenetic tree based on parsimony for another method of deducing a phylogenetic tree, and the results of the substitution would have been predictable. The differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /